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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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John G. Posa
Gifford, Krass, Groh et al
Suite 400
280 N. Old Woodward Ave.
Birmingham, MI 48009

EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/882,889

Applicant(s)

HADDOCK ET AL. 

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 10.
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed November 18, 2002. The Examiner acknowledges the amendments to the specification; the cancellation of claim 4; and the amendments to claims 1, 3, 5-9, 11 and 14. Claims 1-3 and 5-15 are pending.

Information Disclosure Statement

2. The filewrapper for the instant application indicates that five Information Disclosure Statements have been filed. The filewrapper further indicates that two of these Information Disclosure Statements were filed on May 9, 2002. The application file only contains four Information Disclosure Statements. Only one of said four Information Disclosure Statements bears the date of May 9, 2002. The Examiner would like to inquire whether a fifth IDS is missing from the file, or if the IDS filed on May 9, 2002 was mistakenly entered twice on the filewrapper.

This issue was raised by the Examiner in the Office Action mailed August 12, 2002. The Amendment filed on November 18, 2002 was not responsive to this issue. The Examiner requests that the issue be clarified by Applicant in the reply to this Office Action.

Drawings

3. The drawings remain objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “422” has been used to designate both a “rim” as described at page 17, line 10 and a “cable” as described at page 17, line 14. A proposed drawing correction or corrected

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drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

This objection to the drawings was originally made by the Examiner in the Office Action mailed August 12, 2002. The Amendment filed on November 18, 2002 was not responsive to this objection. A proper response to this objection is required in reply to this Office Action.

4. The drawings remain objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: “102” and “104” as illustrated in Fig. 1A and Fig. 1B; “310” and “312” as illustrated in Fig. 3C; “406” as illustrated in Fig. 4A; and “442” as illustrated in Fig. 4D. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

This objection to the drawings was originally made by the Examiner in the Office Action mailed August 12, 2002. The Amendment filed on November 18, 2002 was not responsive to this objection. A proper response to this objection is required in reply to this Office Action.

Claim Objections

5. Claim 5 is objected to because of the following informalities: in line 2, “may continue” apparently should read --continues--. Appropriate correction is required.

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6. Claim 6 is objected to because of the following informalities: in line 8, --adapted to be-- apparently should be inserted before "placed". Appropriate correction is required.

7. Claim 8 is objected to because of the following informalities: in line 3, "finger" apparently should read --fingers--. Appropriate correction is required.

8. Claim 11 is objected to because of the following informalities: in line 2, "basket-like" apparently should read --basket--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-3 and 5-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely

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exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 1 recites the broad recitation "of a vessel wall" and the claim also recites "including an arterial wall" which is the narrower statement of the range/limitation. In line 1 of claim 1, "a vessel wall, including an arterial wall," apparently should read --a vessel wall or an arterial wall,--.

Furthermore, claim 6 recites the broad recitation "of the wall of a vessel" and the claim also recites "including an arterial wall" which is the narrower statement of the range/limitation. In lines 1-2 of claim 1, "the wall of a vessel including an arterial wall," apparently should read --a vessel wall or an arterial wall,--.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the relationship between the catheter and the cantilevered fingers of the temperature sensing tip. This rejection apparently can be overcome by inserting --at the distal end of the catheter-- after "fingers" in line 7 of the claim.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1, 2, 5, 11 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Interventional Thermodynamics, Inc. (WO 92/20290). Interventional Thermodynamics, Inc. teach a catheter system for sensing the temperature of a hollow body organ. The catheter system includes an elongate catheter **54** having a distal end and a proximal end; a sliding filament **58** that protrudes from both ends of the catheter; and a temperature sensing tip including a plurality of presentation elements **57**. Each presentation element **57** is a longitudinal slice of wire, and the presentation elements collectively form a basket-like cage **56**. Each element may have a temperature sensor **61** supported thereon. The proximal ends of the presentation elements are coupled to the distal end of the catheter **54**, and the distal ends of the presentation elements are coupled to the distally protruding end of the filament **58**. The protruding filament at the proximal end of the catheter acts as a manually operated expansion control such that pulling on the control causes each element to move from a retracted position to an expanded position (page 19, lines 1-3) and pushing on the control inherently causes each presentation element to return to the retracted position from the expanded position. A data unit receives signals from the temperature sensors which are thermistors (page 11, lines 21-35). The presentation elements are

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configured such that body fluids may continue to flow around the elements when the elements are in the expanded position. The catheter system inherently can be disposed of after use if a user so desires.

13. Claims 1, 5, 11 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Heuser ('310). Heuser teaches a catheter for thermal evaluation of arteriosclerotic plaque. The catheter includes an elongate catheter body **68** having a distal end and a proximal end; a sliding filament **88** that protrudes from both ends of the catheter; and a temperature sensing tip including a plurality of presentation elements **84a-d**. Each presentation element **84a-d** is a longitudinal slice of wire, and the presentation elements collectively form a wire basket **80**. Each element may have a thermoelectric temperature sensor **82** supported thereon. The proximal ends of the presentation elements are coupled to the distal end of the catheter **68** by a base loop **86**, and the distal ends of the presentation elements are coupled to the distally protruding end of the filament **88**. The protruding filament at the proximal end of the catheter acts as a manually operated expansion control such that pulling on the control causes each element to move from a retracted position to an expanded position and pushing on the control inherently causes each presentation element to return to the retracted position from the expanded position. A data unit in the form of a temperature monitor receives signals from the thermoelectric temperature sensors (paragraph [0035], line 6). The presentation elements are configured such that body fluids may continue to flow around the elements when the elements are in the expanded position. The catheter system inherently can be disposed of after use if a user so desires.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 3 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Interventional Thermodynamics, Inc. (WO 92/20290) in view of Naghavi et al. Interventional Thermodynamics, Inc., as discussed hereinabove, teach all of the limitations of the claims except that the presentation elements are thermally insulative and that the catheter includes at least one thermal sensor to measure a non-wall temperature. Naghavi et al. teach a basket catheter for measuring temperature of a vessel wall. The catheter includes presentation elements that are insulated so that the thermistors mounted thereon are isolated from blood flow. The catheter further includes an “extra” thermistor on the shaft of the catheter that enables the monitoring of the temperature of blood simultaneously. It would have been obvious to one having ordinary skill in the art at the time Applicant’s invention was made to coat the presentation elements of a catheter similar to that of Interventional Thermodynamics, Inc. with a thermal insulative material in view of the teachings of Naghavi et al. in order to isolate the sensors from the effects of body fluid in the vicinity of the organ wall. It further would have been obvious to one having ordinary skill in the art at the time Applicant’s invention was made to include an “extra” temperature sensor on a catheter similar to that of Interventional Thermodynamics, Inc. in view of the teachings of Naghavi et al. in order to simultaneously measure the temperature of body fluids in the vicinity of the organ wall.

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16. Claims 2, 3 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heuser in view of Naghavi et al. Heuser, as discussed hereinabove, teaches all of the limitations of the claims except that the temperature sensors are thermistors; that the presentation elements are thermally insulative; and that the catheter includes at least one thermal sensor to measure a non-wall temperature. Naghavi et al. teach a basket catheter for measuring temperature of a vessel wall. The catheter includes presentation elements that are insulated so that the thermistors mounted thereon are isolated from blood flow. The catheter further includes an “extra” thermistor on the shaft of the catheter that enables the monitoring of the temperature of blood simultaneously. It would have been obvious to one having ordinary skill in the art at the time Applicant’s invention was made to substitute thermistors for the thermocouples of a catheter similar to that of Heuser in view of the teachings of Naghavi et al. as an engineering design choice, simply substituting one known type of thermoelectric sensor for another that is capable of measuring temperature within the body. It further would have been obvious to one having ordinary skill in the art at the time Applicant’s invention was made to coat the presentation elements of a catheter similar to that of Heuser with a thermal insulative material in view of the teachings of Naghavi et al. in order to isolate the sensors from the effects of blood in the vicinity of the organ wall. It further would have been obvious to one having ordinary skill in the art at the time Applicant’s invention was made to include an “extra” temperature sensor on a catheter similar to that of Heuser in view of the teachings of Naghavi et al. in order to simultaneously measure the temperature of blood in the vicinity of the organ wall.

Allowable Subject Matter

17. Claims 6-10 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

18. Claims 13 and 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

19. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 6-10, no prior art of record, alone or in combination, teach or fairly suggest a temperature sensing catheter, as claimed by Applicant, having a distal temperature sensing tip including a plurality of cantilevered fingers, where each finger supports a temperature sensor, and a sliding filament disposed within the catheter, where pulling on the proximal end of the filament causes the fingers to expand outwardly.

Regarding claims 13 and 14, no prior art of record teach or fairly suggest a temperature sensing catheter, as claimed in claim 1, where each presentation element includes a longitudinal groove formed in an outer surface of the element in which the temperature sensor is embedded.

Response to Arguments

20. Applicant's arguments with respect to claims 1-3, 5 and 11-15 have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that Naghavi et al. teach an apparatus having a "passive" design that automatically expands due to the use of shape-

memory alloy, rather than an apparatus such as that claimed in claim 1 where the design is “active” in the sense that a manually operated control is pulled in order to expand the basket structure. Applicant further contends that Brown teaches optical conduits that engage a vessel wall and carry infrared energy to sensors that are located outside the body, rather than the temperature sensors located within the body as claimed in claim 1. These arguments are moot in view of the new grounds of rejection citing Interventional Thermodynamics, Inc. and Heuser, set forth hereinabove, which teach “active” designs and temperature sensors located within the body.

Claims 6-10 are allowable over the prior art of record provided that claim 6 is amended to overcome the rejections under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Claim 11 was rejected under 35 U.S.C. 112, second paragraph, in the Office Action mailed on August 18, 2002 because “the addition of the word ‘like’ to an otherwise definite expression extends the scope of the expression so as to render it indefinite.” The Amendment filed on November 18, 2002 was not responsive to this claim rejection. However, said rejection has since been withdrawn as the expression has been deemed clear in view the detailed description and Figures 2A and 2B. Applicant has been requested in the objection to claim 11 set forth hereinabove to delete “-like” from the expression in order to further clarify the claim language.

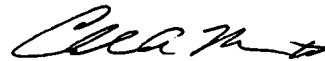
Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nichols teaches a catheter including a basket-like structure that includes temperature sensors mounted thereon and that is activated by pulling on a manually operated control.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Charles A. Marmor, II
Examiner
Art Unit 3736

CAM
January 25, 2003